

We Claim:

1           1. A disposable glucose test strip for use in a  
2           test meter of the type which receives a disposable test  
3           strip and a sample of blood from a patient and performs an  
4           electrochemical analysis of the amount of glucose in the  
5           sample, comprising:

6                 (a) a substrate;  
7                 (b) a reference electrode;  
8                 (c) a working electrode, said working electrode  
9           comprising a conductive base layer disposed on the substrate  
10          and a first working coating disposed over the conductive  
11          base layer, said first working coating comprising a filler  
12          having both hydrophobic and hydrophilic surface regions such  
13          that it forms a network upon drying, an enzyme effective to  
14          oxidize glucose, and a mediator effective to transfer  
15          electrons from the enzyme to the conductive base layer; and  
16                 (d) means for making an electrical connection  
17          between the reference and working electrode and a glucose  
18          test meter.

1           2. The test strip of claim 1, wherein the  
2           working layer is non-conductive.

1           3. The test strip of claim 2, wherein the filler  
2           is silica.

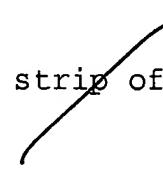
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1                  4. The test strip of claim 3, wherein the  
2 conductive base layer comprises conductive carbon.

1                  5. The test strip of claim 3, wherein the enzyme  
2 is glucose oxidase.

1                  6. The test strip according to claim 3, wherein  
2 the mediator is ferricyanide.

1                  7. The test strip of claim 3, wherein the first  
2 working layer is formed from an aqueous composition  
3 comprising weight 2 to 10 % by weight of a binder 3 to 10 %  
4 by weight of silica; 8 to 20 % by weight of a mediator; and  
5 1000 to 5000 units per gram of the aqueous composition of an  
6 enzyme for oxidizing glucose.

1                  8. The test strip of claim 3, wherein the silica  
Subaid  
is Cab-o-Sil TS610.                  

1                  9. The test strip of claim 8, wherein the  
2 conductive base layer comprises conductive carbon.

1                  10. The test strip of claim 8, wherein the enzyme  
2 is glucose oxidase.

1               11. The test strip of claim 8, wherein the  
2               mediator is ferricyanide.

1               12. The test strip of claim 8, wherein the first  
2               working layer is formed from an aqueous composition  
3               comprising weight 2 to 10 % by weight of a binder 3 to 10 %  
4               by weight of silica; 8 to 20 % by weight of a mediator; and  
5               1000 to 5000 units per gram of the aqueous composition of an  
6               enzyme for oxidizing glucose.

1               13. The test strip of claim 3, further comprising  
2               a second working layer comprising silica, a binder and a  
3               mediator but no glucose-oxidizing enzyme.

1               14. The test strip of claim 3, further comprising  
2               a second working layer comprising silica and a binder but no  
3               glucose-oxidizing enzyme.

1               15. The test strip of claim 1, further comprising  
2               a second working layer comprising a filler, a binder and a  
3               mediator but no glucose-oxidizing enzyme.

1               16. The test strip of claim 1, further comprising  
2               a second working layer comprising a filler and a binder but  
3               no glucose-oxidizing enzyme.

1           17. An aqueous composition comprising a binder, a  
2       ~~silica~~<sup>1</sup> filler having both hydrophobic and hydrophilic surface  
3       regions, at least one of an enzyme effective to oxidize  
4       glucose and an electron transfer mediator.

1           18. The composition of claim 17, wherein the  
2       filler is non-conductive.

1           19. ~~The composition of claim 18, wherein the~~  
2       filler is silica.

1           <sup>19</sup>  
2           <sup>20</sup> 20. An aqueous composition comprising 2 to 10 %  
3       by weight of a binder; 3 to 10 % by weight of silica; 8 to  
4       20 % by weight of a mediator; and 1000 to 5000 units per  
5       gram of the aqueous composition of an enzyme for oxidizing  
glucose.

1           <sup>20</sup>  
2           <sup>19</sup>  
a2           <sup>has</sup> 21. The composition of claim <sup>20</sup>, wherein the  
silica <sup>19</sup> both hydrophobic and hydrophilic surface regions.  
^

1           <sup>21</sup>  
2           <sup>20</sup> 22. The composition of claim <sup>21</sup>, wherein the  
binder is hydroxyethylcellulose.

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1                   22  
23. The composition of claim 20, wherein the  
2 enzyme is glucose oxidase.

1                   23  
24. The composition of claim 20, wherein the  
2 mediator is ferricyanide.

1                   24  
25. A method for making a disposable test strip  
2 for the electrochemical detection of glucose, comprising the  
3 steps of:

4                   (a) applying working and reference electrode  
5 tracks to a substrate;

6                   (b) applying a conductive base layer in contact  
7 with the working electrode track; and

8                   (c) applying a working layer over the conductive  
9 base layer, wherein the working layer comprising a filler  
10 having both hydrophobic and hydrophilic surface regions such  
11 that it forms a network upon drying, an enzyme effective to  
12 oxidize glucose, and a mediator effective to transfer  
13 electrons from the enzyme to the conductive base layer.

1                   25  
26. The method of claim 25, wherein the filler is  
2 non-conductive.

1                   26  
27. The method of claim 26, wherein the filler is  
2 silica.

27  
28. The method of claim 27, wherein the  
2 conductive base layer comprises conductive carbon.

1                         28  
1       29. The method of claim 27, wherein the enzyme is  
2       glucose oxidase.

1                         36                         26  
2         31. The method of claim 27, wherein the first  
3         working layer is formed from an aqueous composition  
4         comprising weight 2 to 10 % by weight of a binder 3 to 10 %  
5         by weight of silica; 8 to 20 % by weight of a mediator; and  
6         1000 to 5000 units per gram of the aqueous composition of an  
enzyme for oxidizing glucose.

33. A disposable glucose test strip which produces a current indicative of the amount of glucose in a sample applied to the strip in response to an applied voltage, wherein the amount of current generated in response

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5 to a given amount of glucose varies by less than 10 percent  
6 over a temperature range from 20°C to 37°C.

*Sub a2*

1 34. A disposable glucose test strip which  
2 produces a current indicative of the amount of glucose in a  
3 sample applied to the strip in response to an applied  
4 voltage, wherein the amount of current generated in response  
5 to a given amount of glucose varies by less than 10 percent  
6 over a hematocrit range of 0 to 60 %.

1 35. A disposable glucose test strip which  
2 produces a current indicative of the amount of glucose in a  
3 sample applied to the strip in response to an applied  
4 voltage, wherein the amount of current generated in response  
5 to a given amount of glucose decays by less than 50% in the  
6 5 seconds following peak current generation.